

Message Text

UNCLASSIFIED

PAGE 01 STATE 099073
ORIGIN HEW-06

INFO OCT-01 AF-10 ARA-10 EUR-12 EA-09 NEA-10 ISO-00
OES-07 EB-07 COME-00 MED-03 /075 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CM
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/OIH:RFISCHER
AF/S:FBCRUMP(INFO)
EUR/EX:JLTULL(INFO)
EA/EX:EECHAMPAGNE(INFO)
NEA/EX:JSCONNOLLY(INFO)
ARA/EX:RSGERSHENSON(INFO)

-----030603Z 104512 /10

P 022124Z MAY 77
FM SECSTATE WASHDC
TO AMEMBASSY PRETORIA PRIORITY
AMEMBASSY MADRID PRIORITY
AMEMBASSY SEOUL PRIORITY
AMEMBASSY SANTIAGO PRIORITY
AMEMBASSY BRUSSELS PRIORITY
AMEMBASSY TEGUCIGALPA PRIORITY
AMEMBASSY CARACAS PRIORITY
AMEMBASSY ROME PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY TEL AVIV PRIORITY
AMEMBASSY MANAGUA PRIORITY
AMEMBASSY DACCA PRIORITY
AMEMBASSY SINGAPORE PRIORITY
AMEMBASSY BONN PRIORITY
AMCONSUL CAPE TOWN PRIORITY

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CAPE TOWN FOR EMB

E.O. 11652: N/A
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TAGS: OGEN, ETRD, EIND, TBIO, SF, KS, CI, BE, HO, VE, IT,
UK, IS, NU, BG, GW, SN

SUBJECT: LABEL MIXUP - BLOOD TYPING SERUM, RECALL
B-010-7

FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: A) HYLAND ANTI-HR (ANTI-E) TYPING SERUM (HUMAN) SLIDE OR RAPID TUBE TEST, 2 ML VIAL,
B) HYLAND ANTI-RHO (ANTI-D) TYPING SERUM (HUMAN) SLIDE OR RAPID TUBE TEST, 5 ML, VIAL.

PRODUCT IDENTIFICATION: A) VIAL LABELED IN PART:
2 ML ANTI-HR (ANTI-E) TYPING SERUM (HUMAN) SLIDE
OF RAPID TUBE TEST U.S. LICENSE NO. 140 HYLAND DIV.
TRAVENOL LABORATORIES, INC., COSTA MESA, CALIF,
92626 LOT NO. 0218A0011 "PAPER INSERT IS INCLUDED
WITH EACH VIAL AND READS IN PART: "ANTI-RH TYPING
SERUM (SERUM (HUMAN) ANTI-HR" (ANTI-E)
DIRECTIONS FOR THE TESTS HYLAND COSTA MESA,
CALIF 00-35-100D REVISED MAY 1973 , EACH
VIAL IS PLACED IN A CARDBOARD BOX WITH A CLEAR WIN-
DOW THROUGH WHICH THE VIAL LABEL CAN BE SEEN. THE
BOX IS LABELED IN PART:"ANTI-RH TYPING SERUM U.S.
LICENSE NO. 140 HYLAND DIVISION TRAVENOL LABORA-
TORIES, INC., COSTA MESA, CALIF. SEE ENCLOSED
DIRECTIONS FOR USE, PRESERVATIVE: SODIUM
AZIDE 0.2 PERCENT (W/V) FOR IN VITRO DIAGNOSTIC
USE - FOR PROFESSIONAL USE ONLY STORE BETWEEN
2 AND 8 C. , LOT NUMBER BEING RECALLED:
0328A001A1.

B) VIAL LABELED IN PART:"5 ML ANTI-RHO (ANTI-D)
TYPING SERUM (HUMAN) SLIDE OR RAPID TUBE TEST
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HYLAND DIV. TRAVENOL LABORATORIES, INC. COSTA
MESA, CALIF., 92626 U.S. LICENSE NO. 140
, A PAPER INSERT IS INCLUDED WITH EACH VIAL
AND READS IN PART: "ANTI-RH TYPING SERUM (HUMAN)
ANTI-RHO (ANTI-D) FOR SLIDE OR RAPID TUBE TESTS
DIRECTIONS FOR THE TEST HYLAND COSTA
MESA, CALIF. 00-35-01-08 OE REVISED SEPTEMBER
1973 . EACH VIAL IS PLACED IN A CARDBOARD BOX
WITH A CLEAR WINDOW THROUGH WHICH THE VIAL LABEL
CAN BE SEEN, THE BOX IS LABELED IN PART: "ANTI-RH
TYPING SERUM U.S. LICENSE NO. 140 HYLAND DIVISION
OF TRAVENOL LABORATORIES, INC., COSTA MESA, CALIF.
92626 SODIUM AZIDE 0.1 PERCENT (W/V) FOR IN VITRO
DIAGNOSTIC USE FOR PROFESSIONAL USE ONLY STORE
BETWEEN 2 AND 8 C. LOT NUMBER BEING RECALLED
0321A003AE.

MFG/RECALLING FIRM: HYLAND DIVISION OF
TRAVENOL LABORATORIES, INC.

3300 HYLAND AVE.
COSTA MESA, CA. 92626

REASON FOR RECALL - HYLAND DIVISION OF TRAVENOL LABORATORIES VERIFIED CUSTOMER COMPLAINT IN THAT VIAL LABELED AS BEING ANTI-RHO (ANTI-D) TYPING SERUM IN ACTUALITY CONTAINED ANTI-HR (ANTI-E)

POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE WHETHER THEY HAVE RECEIVED NOTIFICATION FROM HYLAND DIVISION, TRAVENOL DATED 23 MARCH 1977 REQUESTING CONSIGNEE TO CHECK INVENTORY TO DETERMINE IF THEY HAVE ANY CONTAINERS OF ANTI-RHO (ANTI-D) TYPE SERUM (HUMAN) LOT NUMBER 0321A003AE. SINCE SOME OF THESE UNITS MAY CONTAIN ANTI-HR (ANTI-E) TYPING SERUM (HUMAN) CONSIGNEES ARE REQUESTED TO RECALL ANY OPENED OR UNOPENED ANTI-RHO (ANTI-D) TYPING SERUM, HUMAN, LOT NUMBER UNCLASSIFIED

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00321A003AE AND SHIP BY PRIORITY MAIL TO HYLAND DIVISION RETURNED GOODS DEPT. FOR REPLACEMENT AT NO CHARGE. THEY FURTHER INDICATE THAT ANTI-HR (ANTI-E) VIALS OF THE SAME LOT 0321A003AE ARE SATISFACTORY AND SHOULD NOT BE RETURNED. ANY QUESTIONS CONSIGNEES MAY HAVE REGARD-

ING RECALL SHOULD BE DIRECTED TO FIRM.

FOREIGN CONSIGNEES AS FOLLOWS:

KEAGRAMS, LTD.
P. O. BOX 256 AEROTON
OFF SAMUEL EVANS ROAD
JOHANSBURG, REP OF S.A.

LABORATORIOS HESPERIA SA
XAEROPUERTO MANISES
VALENCIA SPAIN

SEOUL NATIONAL UNIVERSITY
SEOUL,
KOREA

UNIVERSIDAD DE CHILE
HOSPITAL CLINICO
J. J. AGUIRRE
SANTIAGO CHILE, SO.A

TRAVENOL LABS, BELGIUM
SCHENKER & CO. S.A.
C. B. 49, BRUS. NAT.

ARPT., BRUSSELS, BELG

OROQUERIA KARNEL S DE R L
APARTADO POSTAL 952
TEGUCICALPHA,
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HONDURAS

LABORATORIOS BAXTER C.A.
APARTADO 69739
CARACAS, 106
VENEZUELA

TRAVENOL LABS ITALY
FIUMICINO AIRPORT
FIUMICINO ROME, ITALY

ESCUELA DE TECNOLOGIA MED
UNIVERSIDAD DE CHILE
ARICA CHILE

TRAVENOL LABS ENGLAND
CAXTON WAY LONDON R
THETFORD NORFOLK, ENG

TRAVENOL TRADE ISRAEL
P. O. BOX 2
ASHOOD, ISRAEL

COMMERCIAL R. ZAMBRANA, SA
APARTADO POSTAL 502
MANAGUA, NICARAGUA

CHOLERA RESEARCH LABS
MOHAKHALI DACCA 12
BANGLADESH

TRAV INTL GMBH GERMANY 08
ATLANTICK INTL GMBH
8 MUNICH RIEM AIRPORT
GERMANY

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COLD STORAGE SINGAPORE

PTE LTD
18 CHIN BEE AVENUE
JURONG TWN, SINGAPORE
VANCE

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: LABELING, MEDICAL CARE, BLOOD
Control Number: n/a
Copy: SINGLE
Sent Date: 02-May-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE099073
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CM
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770154-0083
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t197705102/aaaadlaa.tel
Line Count: 228
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: ce2ce287-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 5
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 14-Oct-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2327549
Secure: OPEN
Status: NATIVE
Subject: LABEL MIXUP - BLOOD TYPING SERUM, RECALL B-010-7 FDA ADVISES OF THE FOLLOWING RECALL
TAGS: OGEN, ETRD, EIND, TBIO, SF, KS, CI, BE, HO, VE, IT
To: PRETORIA MADRID MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/ce2ce287-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009